What FDA Learned About Dark Chocolate and Milk Allergies

NOTE: This Consumer Update sheds further light on the results of an FDA study on milk in dark chocolate shared in an earlier story. More in-depth study results can be found at: www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/ucm446646.htm

If you're allergic to milk and you love dark chocolate, how do you know whether you can indulge in a candy bar without having an allergic reaction? That's what the Food and Drug Administration (FDA) wanted to learn, especially after receiving reports that consumers had harmful reactions after eating dark chocolate.

Milk is a permitted ingredient in dark chocolate, but it is also one of eight major food allergens (substances that can cause reactions that are sometimes dangerous). U.S. law requires manufacturers to label food products that are major allergens, as well as food products that contain major allergenic ingredients or proteins. Allergens contained in a food product but not named on the label are a leading cause of FDA requests for food recalls, and undeclared milk is the most frequently cited allergen. Chocolates are one of the most common sources of undeclared milk associated with consumer reactions.

FDA tested nearly 100 dark chocolate bars for the presence of milk. Earlier this year, the agency issued preliminary findings, and is now releasing more information about its research. The bars tested by FDA were obtained from different parts of the U.S., and



Examples of messages found on some dark chocolate products.

each bar was unique in terms of product line and/or manufacturer. Bars were divided into categories based on the statements on the labels.

The bottom line? Unfortunately, you can't always tell if dark chocolate contains milk by reading the ingredients list. FDA researchers found that of 94 dark chocolate bars tested, only six listed milk as an ingredient. When testing the remaining 88 bars that did not list milk as an ingredient, FDA found that 51 of them actually did contain milk. In fact, the FDA study found milk in 61 percent of all bars tested.

In part, that's because milk can get into a dark chocolate product even when it is not added as an ingredient. Most dark chocolate is produced on equipment that is also used to produce milk chocolate. In these cases, it is possible that traces of milk may inadvertently wind up in the dark chocolate.

Read 'May' as 'Likely'

To inform consumers that dark chocolate products may contain milk even if not intentionally added, many chocolate manufacturers print "advisory" messages on the label. There's quite a variety of advisory messages, such as:

- "may contain milk"
- "may contain dairy"
- "may contain traces of milk"
- "made on equipment shared with milk"
- "processed in a plant that processes dairy"
- "manufactured in a facility that uses milk"

FDA found that milk was present in 3 out of every 4 dark chocolate products with one of these advisory statements. Some products had milk levels as high as those found in products that declared the presence of milk.

When the National Confectioners Association (NCA) was asked for its advice, a spokesperson said that "consumers with milk allergies should not consume dark chocolate products that come with advisory statements, since these products may indeed contain milk proteins."

Another problem is that advisory messages may appear to be conflicting if they are accompanied by dairy-free or vegan statements. "Even a consumer who carefully reads the label may be confused by a statement such as "vegan" (which implies that no animal-derived products were used) along with an advisory—or "may contain" statement—referring to the presence of milk," says Stefano Luccioli, M.D., a senior medical advisor at FDA.

Not Quite 'Dairy Free'

In addition to these advisory statements, labels for chocolate bars may make other claims. Some say "dairy-free" or "lactose free," but FDA found milk in 15% of the dark chocolates with this label. And 25% of dark chocolate products labeled only "vegan" were found to contain milk.

No Message Doesn't Mean No Milk You shouldn't assume that dark chocolate contains no milk if the label does not mention it at all. "Milkallergic consumers should be aware that 33% of the dark chocolates with no mention of milk anywhere on the label were, in fact, found to contain milk," says Luccioli.

What Consumers Can Do

- Consumers who are sensitive or allergic to milk should know that dark chocolate products are a high-risk food if you're highly milk-allergic.
- 2. Start by checking the ingredients list to see if it includes milk.
- 3. Read all the label statements on dark chocolate products and avoid those with an advisory statement for milk, even if these products feature also other (and

Label/Package Statement	Total number of dark chocolate products	Number and percent (%) of dark chocolate products testing positive for milk
Milk (or milk-derived components¹) listed as ingredient	6	6 (100%)
Advisory statments ² (alone or combined)	59	44 (75%)
Dair-free or lactose-free ³ statements alone	13	2 (15%)
Vegan statement alone	4	1 (25%)
No statement regarding milk	12	4 (33%)
TOTAL	94	57 (61%)

- 1. Some examples of milk components include cream, milk fat, and sodium caseinate.
- 2. Advisory statements refers to statements regarding the possible presence of milk, such as "may contain milk (or dairy)", "made on equipment shared with milk," "processed in a plant that processes dairy", or "manufactured in a facility that uses milk." This category also includes "may contain traces" statements, as well as advisory statements combined with either a vegan or dairy-free or lactose statement
- 3. Lactose-free chocolates are grouped with dairy-free products although the statement "lactose-free" does not necessarily indicate that the product is free from milk. This is because lactose is a "milk sugar," and its removal does not mean that milk proteins are removed as well.
 - conflicting) statements, such as "dairy-free" or "vegan".
- 4. View even products with dairy-free claims or without any mention of milk with caution, unless the manufacturer is a trusted source and/or uses dedicated equipment for making milk-free chocolate products.

"The chocolate industry will continue to make every effort to understand the needs of allergic consumers and communicate the potential presence of milk allergens in dark chocolate through advisory labeling," says Laura Shumow, director of scientific and regulatory affairs at NCA.

FDA is evaluating the study findings and considering options for addressing the issues identified in the study. Further, allergen contamination is included in the preventive and risk-based controls mandated by the FDA Food Safety Modernization Act (FSMA). Under the proposed

Preventive Controls for Human Food rule that is scheduled to become final this fall, food manufacturers would be required to implement a food safety plan that identifies safeguards in place to prevent or significantly reduce such hazards as food allergens.

The proposed rule includes provisions to prevent unintended cross-contact between foods that contain allergens and those not intended to contain them. Firms covered by the final rule would have from one to three years after the rule becomes final to comply, depending on the size of the firm.

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